

IMDMC



INDIANA MEDICAL DEVICE MANUFACTURERS COUNCIL, INC.

November 30, 1999

Dockets Management Branch  
**HFA-305**  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket No. 99D-2873

Dear Sir or Madam:

The Indiana Medical Device Manufacturers Council, Inc. (IMDMC) endorses the comments submitted by the HIMA Least Burdensome Task Force, a coalition of members from the medical device industry, submitted on November 24, 1999, to FDA regarding the "Draft Guidance on Evidence Models for the Least Burdensome Means to Market." Several associations within the medical device industry, including ours, have serious concerns with the draft guidance circulated for comment by FDA. We believe a major redrafting of this guidance is required.

We also believe that a cooperative effort between FDA and industry through working groups has proven to be a more effective mechanism for developing guidances of this type. We appreciate the FDA's willingness to consider these comments and express our desire to work with FDA on this very important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Karen G. Burch". The signature is fluid and cursive.

Karen G. Burch  
Executive Director

cc: Janet Trunzo, HIMA  
Neal Feamot, MED Institute  
Bradley M. Thompson, Baker & Daniels

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**FACSIMILE TRANSMISSION**

**TO:** FDA **Dockets** Managements Branch – **HFA-305**

**FROM:** **Karen G. Burch, Exccutive Director**  
Indiana **Medical Device Manufacturers** Council Administrative **Office**

**DATE:** November 30, 1999

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**RE:** **Following is a letter** regarding FDA's "**Draft** Guidance **on Evidence**  
Models for **the** Least Burdensome Means to Market."